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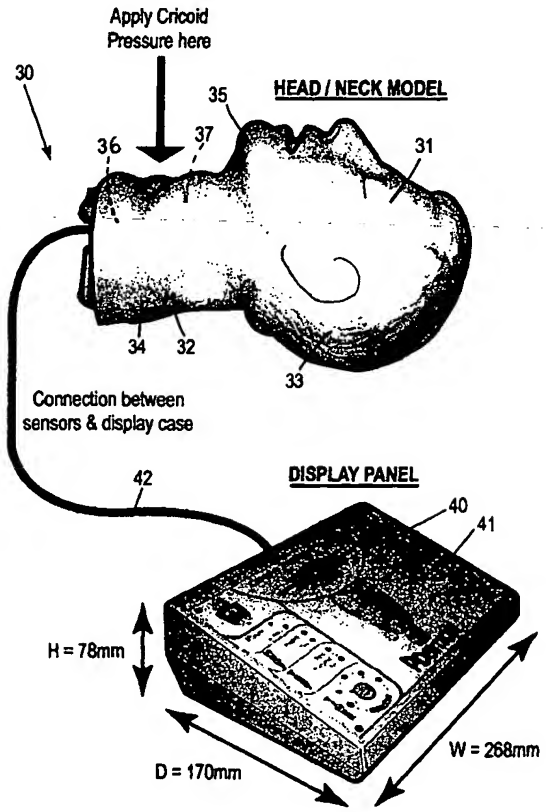

(57) Abstract: A method and apparatus (30) for training correct application of pressure to a body part particularly, but not exclusively, application of cricoid pressure. The apparatus includes: a pressure sensing device (38) for measuring the magnitude of pressure applied to the body part; and position sensing means (50) for detecting a location at which pressure is applied relative to the body part.

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METHOD AND APPARATUS FOR MEASURING APPLICATION OF PRESSURE TO AN IMITATION BODY PART

Field of the Invention

The present invention relates to a method and apparatus for measuring application of pressure to an imitation body part and particularly, but not exclusively, to use of such apparatus as a training aid for correct application of cricoid pressure or Sellick's manoeuvre.

Background of the Invention

Training aids are routinely used for a variety of medical procedures. Products such as the ResusciAnne® mannequin are used as part of CPR training, defibrillation training, and trauma management. It has been recognised that regular staff training with such devices improves the skill level of the trainee by providing a realistic simulation of the procedure. By improving the skills of medical personnel, lives can be saved in emergency situations where a prompt, accurate response is required. There has not to date, however, been an adequate training aid for correct application of cricoid pressure.

History

By way of background information, reference to cricoid pressure (CP) can be found from as early as the 1770's, where the application of some force on the larynx was used to prevent gastric distension during inflation of the lungs in drowned subjects (Brimacombe, 1997). It wasn't until 1961 that B.A. Sellick developed a technique using CP to prevent regurgitation of gastric contents during induction of anaesthesia. The same manoeuvre could also be used to prevent inflation of the stomach resulting from positive pressure ventilation. It is for his work in developing this CP technique that it was named "Sellick's Manoeuvre".

To this day, Sellick's manoeuvre is used as the standard practice when performing rapid sequence intubations. The technique is most commonly used when performing emergency surgery or caesarean sections. Administering anaesthesia can cause patients to regurgitate

any contents they may have in their stomach. It is for this reason that patients must fast before a *scheduled* operating procedure. However, in *emergency* situations patients have not had the opportunity to fast, and are likely to have full stomachs. Administration of anaesthetic would therefore cause the patient to vomit. The regurgitated contents can sit in their airway and run down the trachea and flood the lungs. Flooding of the lungs can be a fatal condition. By applying the appropriate force to the cricoid cartilage, regurgitation of stomach contents can be prevented.

Anatomy of the Larynx

An appreciation of the anatomy of the neck and larynx is vital in understanding the theory behind Sellick's manoeuvre. Figure 1 shows the anatomy of the larynx. The cricoid cartilage 1 is a C-shaped ring of cartilage. It forms part of the larynx 2 and is located at the top of the trachea 3 (windpipe), but below the thyroid cartilage 4 (Adam's apple). The cricoid cartilage is attached anteriorly to the thyroid cartilage via the cricothyroid ligament 5 and is filled at either side by the cricothyroid muscle (not shown). The cricotracheal ligament 6 attaches the inferior side of the cricoid cartilage to the first of the tracheal cartilage rings 7.

Running behind the larynx is the oesophagus and pharynx. The pharynx extends from the mouth down to the level of the cricoid cartilage where it becomes the oesophagus. The top of the oesophagus is located between the cricoid cartilage and the 5th cervical vertebra of the spine.

Cricoid Pressure Theory

Sellick first described the technique for applying cricoid pressure in an article of the *Lancet* in 1961. He described the manoeuvre as providing "temporary occlusion of the upper end of the oesophagus by backward pressure of the cricoid cartilage against the bodies of the cervical vertebrae". Figure 2 shows clearly the effect on the oesophagus 8 when applying cricoid pressure. The circled region 9 indicates the blocked oesophagus; this prevents regurgitation of stomach contents.

Figure 3 shows the correct method for applying cricoid pressure, as described by Sellick in

1961. This is known as the single-handed cricoid pressure (SHCP) technique. Once anaesthesia begins an assistant uses the thumb, index finger and middle finger to apply pressure. The pressure is released once intubation of the patient has been completed. Sellick concluded that the technique be used to *"occlude the oesophagus (a) to control regurgitation of stomach contents during induction of anaesthesia, or (b) to prevent gastric distension from positive-pressure ventilation"* (Sellick, 1961).

Recommended Practice

Although Sellick suggested the mechanisms of applying cricoid pressure, he did not quantitatively describe how much pressure should be applied; only that *firm* pressure be used. Since his article was published in 1961 several studies have been carried out to evaluate the optimal conditions for applying cricoid pressure. Advances in medical technology have also prompted the need for re-evaluation of Sellick's original procedure.

The accepted optimal method for CP involves using the SHCP technique with firm neck support using a non-collapsible intubating pillow (Brimacombe, 1997). After pre-oxygenation, a cricoid pressure of approximately 20N should be applied to the patient while a muscle relaxant is administered. Suxamethonium is usually used as the muscle relaxant; however, this has some unwanted and occasionally severe side effects. There is a shift towards using a substance called nocuronium instead of suxamethonium, but this is slower in onset and requires cricoid pressure to be applied for longer periods. After approximately 45 seconds the muscle relaxant has entered the bloodstream and taken effect. At this point the CP should be increased to 40N while the patient is intubated. The force of 40N may need to be held constant for up to five minutes while an assistant performs the intubation. Cricoid pressure is released once the patient has been correctly intubated.

Several sources, including Brimacombe & Berry, highlight the need for teaching staff the recommended procedure of applying cricoid pressure.

Literature Review

Several studies have been performed to evaluate the technique of anaesthetists, and

anaesthetic assistants, in applying cricoid pressure. Although a number of different methods are used to teach staff the correct procedure, each study obtained comparable results and drew similar conclusions.

Previous Techniques

Study #1

A study by Ashurst et al. in 1996 aimed to assess the performance of anaesthesia personnel in applying cricoid pressure using a simulator model. Staff took part in a brief training programme using the model, and their ability to retain these skills was also evaluated using the simulator. Figure 4 shows the device 20 that was used to evaluate cricoid pressure.

The device 20 consisted of a Perspex plunger 21 attached to a yoke 22 that was placed over the cricoid cartilage 23 of a Laerdal® airway management trainer 24. A transducer 25 was used to convert the diaphragm pressure created by pressing the plunger, into an electronic signal. The force was displayed as a moving line and recorded using an oscilloscope 26. Forces of 5N to 60N could be recorded accurately.

Anaesthetic personnel were asked to apply forces of 20N and 40N using the SHCP technique to the simulator. Each force was held for 20 seconds. Initial readings were taken before training began, with the trainee unable to see the force output on the oscilloscope. Subsequent training took place over several days, in which the trainees were allowed to view the force on the oscilloscope. Some of the staff were assessed three weeks later to evaluate skill retention. The attempt was to train staff in applying the appropriate 20N and 40N forces within the respective ± 2.5 - 5N range.

Although this method provides accurate force measurements, there are some limitations and problems with the device. Firstly, it assumes that a "cricoid yoke" is used to apply the cricoid pressure. The practice in countries, such as Australia, however is to use the three-finger technique directly to the skin of the patient. Therefore, the use of a yoke would decrease the reproducibility of the technique in real-life. Secondly, using an oscilloscope would require mains power and constant calibration of the device. Finally, the device does not test the trainee's ability to *find* the cricoid cartilage; it only evaluates the amount of

force being used.

Study #2

A 1996 study by Herman, Carter, and Van Decar aimed to establish whether with education and practice, anaesthetic assistants could be taught the recommended cricoid pressure and retain the skill. The simulator model used in this study was very basic. A life-size laryngotracheal training model was placed on a set of infant scales that displayed the pressure applied to the model in terms of kilograms.

Participants were asked to apply 20N of pressure to simulate "awake" patients, and 40N for simulating cricoid pressure on "anaesthetised" patients. Data was taken at four stages of the training programme; before instruction; after instruction on how much force should be applied; after a practice period; and at a follow-up session 3 months later.

Advantages of this system include that it is portable and simple to use. However, it does have some limitations and disadvantages. Firstly, the readout on the infant scales is displayed in kilograms. Most literature describes cricoid pressure in Newtons, and hence, it would be better to use these units for feedback. Another limitation is in the laryngotracheal model. This model is made of a rigid plastic that does not "simulate" the compressibility or elasticity of a real-life human larynx and neck. Finally, this method only studies the magnitude of the cricoid pressure; it does not evaluate the location or the direction of the applied force.

Study #3

In a study by Meek, Vincent, & Duggan (1998) a "home-made" cricoid pressure trainer was used to evaluate anaesthetic assistants. Their model was made "using a 4cm diameter Perspex universal container with a collar of oxygen tubing to form the cricoid cartilage, all covered with Granuflex dressing to simulate skin" (Meek, 1998). The applied cricoid force was measured using a load cell (0-20kg capacity, ±0.03% accuracy), and displayed using a calibrated chart recorder.

Although this device is reasonably accurate, it does have some disadvantages. The "home-made" larynx model is far from life-like, and a chart recorder must be used. This would

limit the portability of the unit, and requires knowledge of how to use and calibrate the chart recorder. Similar to the other studies, this method does not indicate the location of the force being applied. The staff member could be applying the correct force, but in the wrong location. This fault could be fatal in a real life situation if the mistake is not detected.

Results from Previous Studies

Ashurst et al. reported mean initial forces of 16.8N and 32.9N compared to target forces of 20N and 40N respectively. In fact, 61% of the 49 participating subjects could not reach an adequate force (>35N) before training. After the brief training programme, nearly all subjects were able to produce results within the accepted range. Even after a period of three weeks, most of the subjects retained the ability to apply appropriate cricoid pressure.

Herman et al. also reported lower than required forces before training. For the target forces of 20N and 40N the average force applied before instruction was 16.2N ±1.7N and 20N respectively. After the subjects were instructed the performance increased to 20.3N ±1.7N and 30.8N ±2.1N. After a practice period with the trainer, the forces remained within the accepted range at 22.2N ±0.1N and 39.0N ±1.4N. The follow-up test 3 months later showed no marked decreased in the trainee's ability to apply the appropriate cricoid pressure at 20N or 40N.

Results from Meek et al. (1999) highlighted a lack of knowledge relating to Sellick's manoeuvre. They reported that only one third of anaesthetic assistants could quote appropriate cricoid forces, and that very few assistants had been trained using a model before practising the technique on patients. Furthermore, technique was poor and there was a large range of forces applied.

Other studies produced very similar results regardless of the technique they used to simulate cricoid pressure (Howells, 1983; Meek, 1998). In all cases, initial assessment revealed that there was inadequate force applied to the simulator and that forces could not be maintained for any length of time. The studies also revealed that through appropriate training methods the majority of staff was able to maintain forces more accurately and for

longer periods. Some studies also found that the knowledge acquired during training could be retained for several months without loss of performance.

Conclusions & Recommendations

Ashurst et al. (1996) concluded that training improves performance, but that some staff may be "untrainable". They also suggested that staff undertake a frequent training regime, but did not suggest the frequency of the training.

Herman et al. suggested that cricoid pressure could be learned over a short period and that even after a single training session, the skills could be retained for 3 months. It was also noted that assistants could not reach the required 40N level *until* they practiced the technique using the trainer. The reason for this was that most of the subjects had been using a relative comparison method to judge how much force to apply. This method suggests applying pressure "sufficient to cause pain if applied to the bridge of the nose" (Herman, 1996). This method resulted in subjects applying 10N – 20N less force than is required.

These, and other studies, highlight the need for a cricoid pressure trainer that is realistic and provides appropriate feedback. There is currently no device on the market which provides a life-like training model *and* an accurate and easy to understand output.

Object of the Invention

An object of the invention is to provide an apparatus which may be better used as a trainer for applying pressure to a body part particularly, but not exclusively, for application of cricoid pressure.

Summary of the Invention

In accordance with the present invention, there is provided an apparatus for measuring application of pressure on an imitation body part including:

a pressure sensing device for measuring the magnitude of pressure applied to the body part; and

position sensing means for detecting a location at which pressure is applied relative

to the body part.

Preferably, the apparatus further includes a direction sensor for identifying the direction in which the pressure is applied to the body part.

Preferably, the apparatus includes a timer for indicating the duration during which pressure is applied to the body part.

Preferably, the position sensing means includes force sensing elements located at either side of the body part.

Preferably, the apparatus includes a mannequin having at least an imitation throat region and the body part is the cricoid cartilage.

Preferably, the throat region is mounted in a neck portion of the mannequin, for limited movement therebetween, and the direction sensor identifies movement of the throat region relative to the neck portion during application of the pressure, to thereby provide an indication of the direction in which the pressure is applied.

Preferably, the mannequin is provided with a skin-like material covering the position sensing means and sensing device.

Preferably, the apparatus includes a display for providing a visual indication of the magnitude of the pressure applied, output from the pressure sensing device, and the location of which the pressure is applied.

Preferably, the display also provides a visual indication of the output of the direction sensor.

Preferably, the display is provided in a display unit with the timer.

In another aspect, there is provided a method for training a person in application of correct location and magnitude of pressure on a body part, using the above-described apparatus. Preferably, the method is for training application of cricoid pressure.

Brief Description of the Drawings

The invention is described in more detail, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Figure 1a is a front view of a larynx structure;

Figure 1b is a cross-section side view of the larynx structure of Figure 1a;

Figure 2a is an x-ray showing a lumen of the upper oesophagus filled by a latex tube containing contrast medium;

Figure 2b is an x-ray showing closure of the oesophagus by cricoid pressure;

Figure 3a illustrates an extended position of a neck and the application of cricoid pressure;

Figure 3b is a diagram showing the cricoid pressure manoeuvre;

Figure 4 is a diagrammatic representation of cricoid force applied with a "yoke";

Figure 5 is a representation of an apparatus, in accordance with the invention;

Figure 6 illustrates the positioning of sensors in the apparatus; and

Figure 7 is a representation of a display panel of the apparatus of Figure 5.

Detailed Description

Referring firstly to Figure 5, the apparatus 30 is shown as including a life-like mannequin/model 31, to simulate the look and feel of a real human patient. A Laerdal mannequin has been used as the base for the trainer's life-size head/neck model. It consists of a life-like "skin" 32 which covers the head 33 and neck portion 34; a moveable lower jaw 35; internal oesophagus and trachea 36; and a larynx 37. The larynx, which represents the throat region of the model is mounted in the neck portion 34 for limited relative movement therebetween.

The apparatus further includes a display unit 40 which houses a printed circuit board (PCB), battery, plugs, and switches (not shown) and has a removable display panel 41 that forms the front of the display unit 40. A conventional 3 metre, 9-pin D connector computer cable 42 can be used to connect the unit to sensors within the neck model 31.

The display panel 41 indicates how much force is being applied to the cricoid cartilage

and, for that purpose, a number of sensors are fitted to the model 31 and coupled to respective circuitry in the unit 40 to allow the output of the sensors to be displayed on the panel. The sensors are shown in Figure 6, which depicts the model 31 with the skin removed from the neck portion 34. The sensors comprise position sensing elements in the form of force sensing resistors (FSRs) 50 located along either side of the larynx 37, to detect the location at which pressure is applied to the larynx, and direction sensors 51 in the form of microswitches 52, which are actuated by movement of the larynx 37 relative to the neck portion 34. A further pressure sensing device (not shown) is provided beneath the larynx to detect the magnitude of the applied pressure. With regard to the specific placement of the FSRs, these are located on the Adam's apple and trachea to detect forces that are applied too high, or too low respectively. Smaller FSRs are mounted on the cricoid cartilage to detect the correct application of forces.

Note that two FSR's are used at each of the three locations, with one FSR located either side of the mid-line of the larynx. As described earlier, this is done to detect correct and incorrect application of cricoid pressure. The position of the applied pressure will only register if *both* of the FSR's of each pair are activated at the same time. Hence, the trainee needs to apply pressure using the *correct technique* for the position of the force to be detected.

FSR's are also useful due to their slim design. Because the FSR's are so thin, they are undetectable under the skin of the mannequin. This prevents trainees finding the correct location by simply feeling for "lumps" under the skin. As such, wear and tear on the skin of the mannequin will be reduced, which will also assist in concealing the location of the FSR's.

The unit 40 is designed to provide sufficient feedback regarding the forces being applied to the sensors of the model 31 and to indicate correct application of cricoid pressure. The display panel therefore indicates four primary factors regarding the cricoid pressure; these being (1) the *magnitude* of the cricoid pressure; (2) the *position* of the applied force; (3) the *direction* of the force; and (4) the *duration* of the force.

To indicate the *amount* of force applied to the cricoid cartilage a LED bar graph display 60

is used (see Figure 7). This provides a highly visual indicator that is easy to associate with the force being applied. Four multi-coloured LED bar displays, each containing 10 LED's, are mounted one on top of the other in a vertical fashion. This produces a single bar graph display containing 40 LED's. A range from 10N to 50N can then be displayed, with a resolution of 1N per LED. Of course, alternative units may be used instead of Newton units, as appropriate.

By using multi-coloured LED's it is possible to use green LED's to indicate the *correct* forces at 20N and 40N respectively and as the force strays from these values, the LED's change colour. If the force is close to 20N or 40N then yellow LED's are activated, as the force varies greatly from these values red LED's are used. This colour scheme is consistent with the traditional belief that green indicates something that is "safe" or "correct", and red implies "dangerous" or "incorrect". The colour combination for each LED bar display is as follows: R R R Y Y Y Y G G G.

LED's 61 are also used on the display panel to indicate where the force is being applied in relation to the cricoid cartilage, in accordance with output from the force sensing resistors 50. A green indicator 62 is used for forces applied correctly on the cricoid cartilage, and red LED's 63 are used to indicate forces that are applied elsewhere. Yellow indicators 64 provide information on whether the larynx is being forced sideways instead of directly toward the back of the neck, in accordance with output from the sensors 51.

A selectable timer 65 is required to time the duration of the applied cricoid pressure. There needs to be 5 selectable times from 1-5 minutes; this is the usual range of periods that cricoid pressure is applied in practice. The timer indicator will show how long the 40N cricoid pressure needs to be held to pass the test. The timing circuit signals when the trainee needs to increase the pressure to 40N and also when to stop the procedure. A small piezo buzzer is used for this purpose. The timer is connected to a "Mode" switch 66. When in "Practice" mode, the trainer only provides feedback regarding the *position* and *magnitude* of the force. When "Test" mode is selected, the *timer* is also activated to *test* the ability of the trainee to hold the force that they have practiced.

The timer may drive a small piezo buzzer which sounds for 1 second and a second buzzer

which sounds for 2 seconds. After 45 seconds of applying cricoid pressure, the first buzzer sounds to indicate to the trainee that the force needs to be increased from 20N to 40N. After the selected time period (1-5min.), the second buzzer indicates to the trainee that they should cease applying pressure.

One of the main design objectives of the invention was to provide simple, yet adequate, feedback on how the cricoid pressure is being applied. It is vital for learning and teaching purposes that the trainer is easy to use and understand. Importantly, the trainee should be able to associate what they see on the display panel with what they are actually doing. For that purpose the final design of the front panel display includes a central graphical representation of a larynx, which is used to indicate the *position* of the applied force, with the indicating LED's 61 appropriately located to show, as mentioned above, *green* (correct position on the cricoid cartilage), *yellow* (direction of force, left or right), and *red* (wrong position on the larynx). To further correlate with the corresponding positioning on the model, this section of the panel may be "flesh" coloured to represent the neck of the Laerdal model, with the arc at the top of the larynx representing the lower jaw.

Text boxes may also be provided at the left of the bar graph 60, to describe each step of the procedure to facilitate self-teaching. Brackets stemming from these text boxes indicate the region in which the force should be held for that particular step.

To the left of the panel are the other indicators and switches included in the design. An on/off switch 67, power indicator 68, and low battery LED 69 are included for obvious reasons.

Additional improvement or modifications to the unit may include:

- Replacing the current display panel with a large LCD display.
- A test function that returns a result of how well the trainee performed, based on; the average force applied, the duration of the applied force, where the force was applied, and the standard deviation from the target forces.
- Voice commands that tell the trainee when to increase pressure and when to stop.
- A display panel with electronic touch buttons instead of mechanical switches.

- Replacing the connector cable with remote control cordless operation.

The model may also be provided with several different neck "skins". The skins would be removable and represent a number of different patient types. The current prototype has what would be considered a "normal male" neck skin. Other skins which could be developed include; an "obese patient" with extra padding; a "female" with less prominent Adam's apple; and a "child" model.

As may be appreciated from the above, the apparatus of the invention has been described with reference to training of correct application of cricoid pressure but may also be suitable for any application where training is required for applying both correct location and magnitude of pressure on a body part.

The Claims:

1. An apparatus for measuring application of pressure on an imitation body part including:

   a pressure sensing device for measuring the magnitude of pressure applied to the body part; and

   position sensing means for detecting a location at which pressure is applied relative to the body part.

2. An apparatus as claimed in claim 1, wherein the position sensing means includes force sensing elements located at either side of the body part.

3. An apparatus as claimed in claim 1 or 2, further including a timer for indicating the duration during which pressure is applied to the body part.

4. An apparatus as claimed in any one of claims 1 to 3, further including a direction sensor for identifying the direction in which the pressure is applied to the body part.

5. An apparatus as claimed in any one of claims 1 to 3, further including a mannequin having at least an imitation throat region and the body part is the cricoid cartilage.

6. An apparatus as claimed in claims 4 and 5, wherein the throat region is mounted in a neck portion of the mannequin, for limited movement therebetween, and the direction sensor identifies movement of the throat region relative to the neck portion during application of the pressure, to thereby provide an indication of the direction in which the pressure is applied.

7. An apparatus as claimed in claim 5 or 6, wherein the mannequin is provided with a skin-like material covering the position sensing means and sensing device.

8. An apparatus as claimed in any one of claims 1 to 7, further including a display for providing a visual indication of the magnitude of the pressure applied, output from the pressure sensing device, and the location of which the pressure is applied.

9. An apparatus as claimed in claim 8, wherein the display also provides a visual indication of the output of the direction sensor.

10. An apparatus as claimed in claim 8 or 9, wherein the display is provided in a display unit with the timer.

11. A method of training the application of correct location and magnitude of pressure on a body part, using the apparatus of any one of claims 1 to 10.

12. A method as claimed in claim 11, for training application of cricoid pressure.

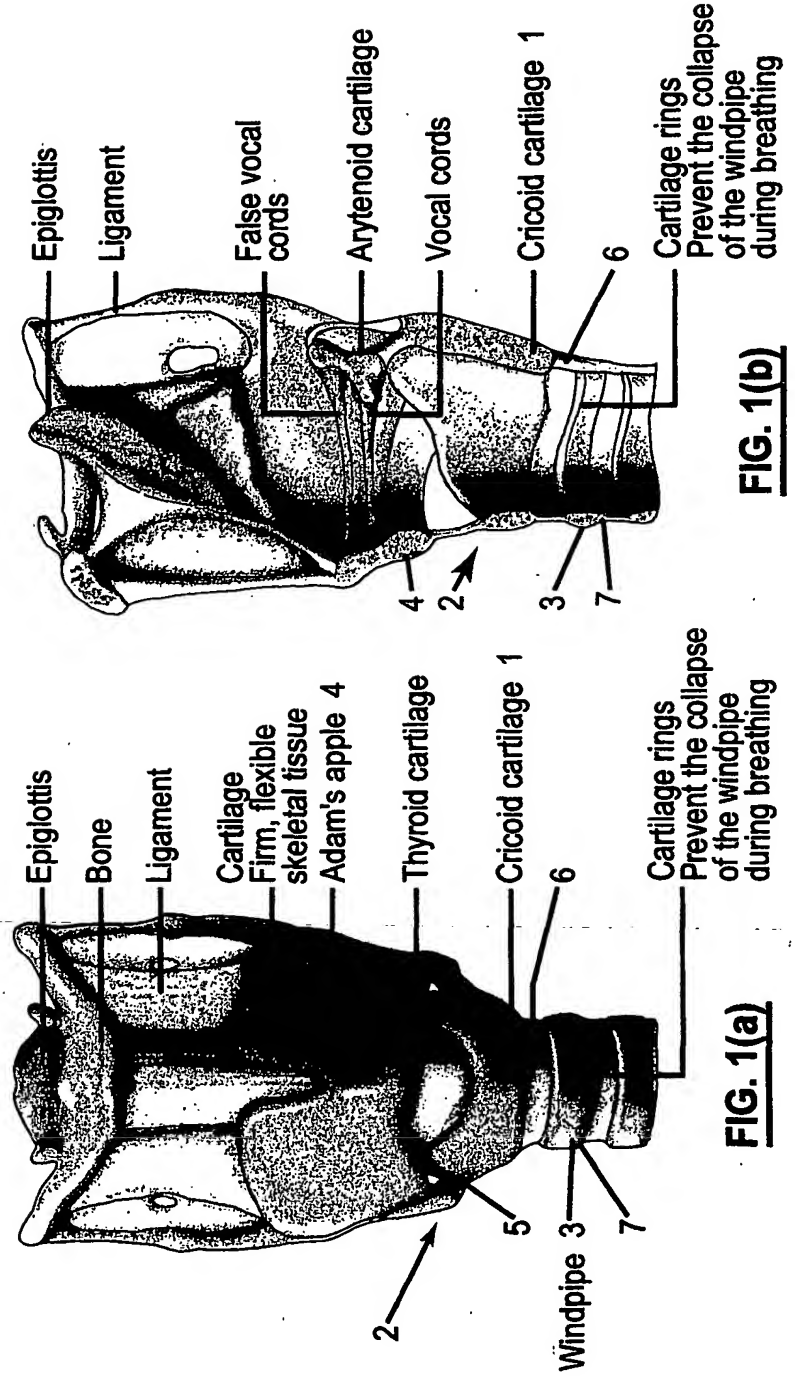
Epiglottis
Bone
Ligament
Cartilage
Firm, flexible
skeletal tissue
Adam's apple 4
Thyroid cartilage
Cricoid cartilage 1
6
Cartilage rings
Prevent the collapse
of the windpipe
during breathing
2
Windpipe
5
3
7
Epiglottis
Ligament
False vocal
cords
Arytenoid cartilage
Vocal cords
Cricoid cartilage 1
6
Cartilage rings
Prevent the collapse
of the windpipe
during breathing
4
2
3
7

FIG. 1(a)

FIG. 1(b)

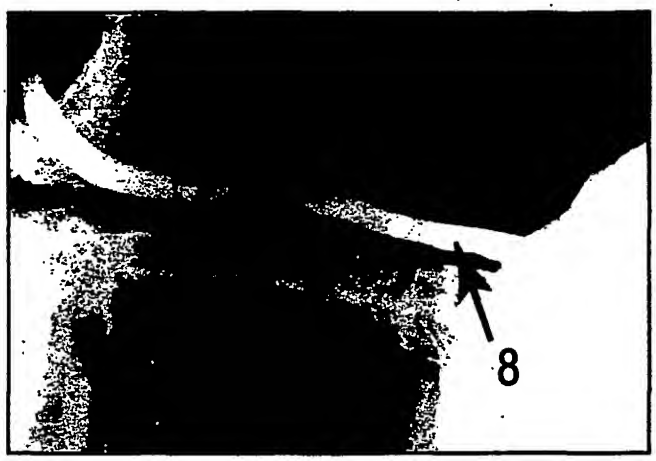

FIG. 2(a)

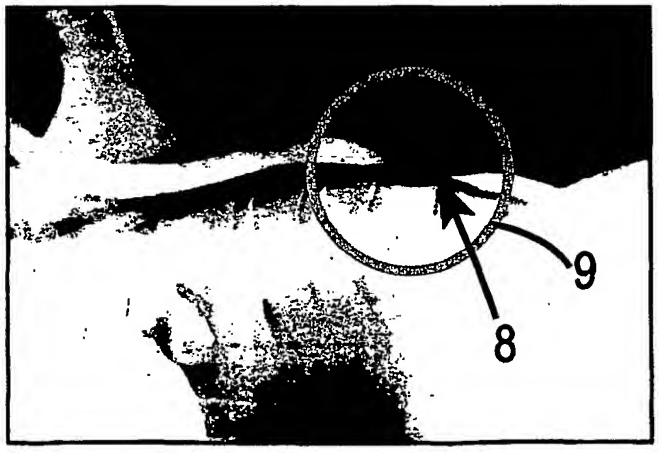

FIG. 2(b)

FIG. 3(a)

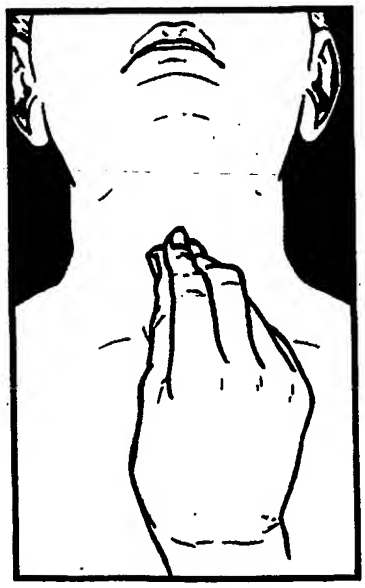

FIG. 3(b)

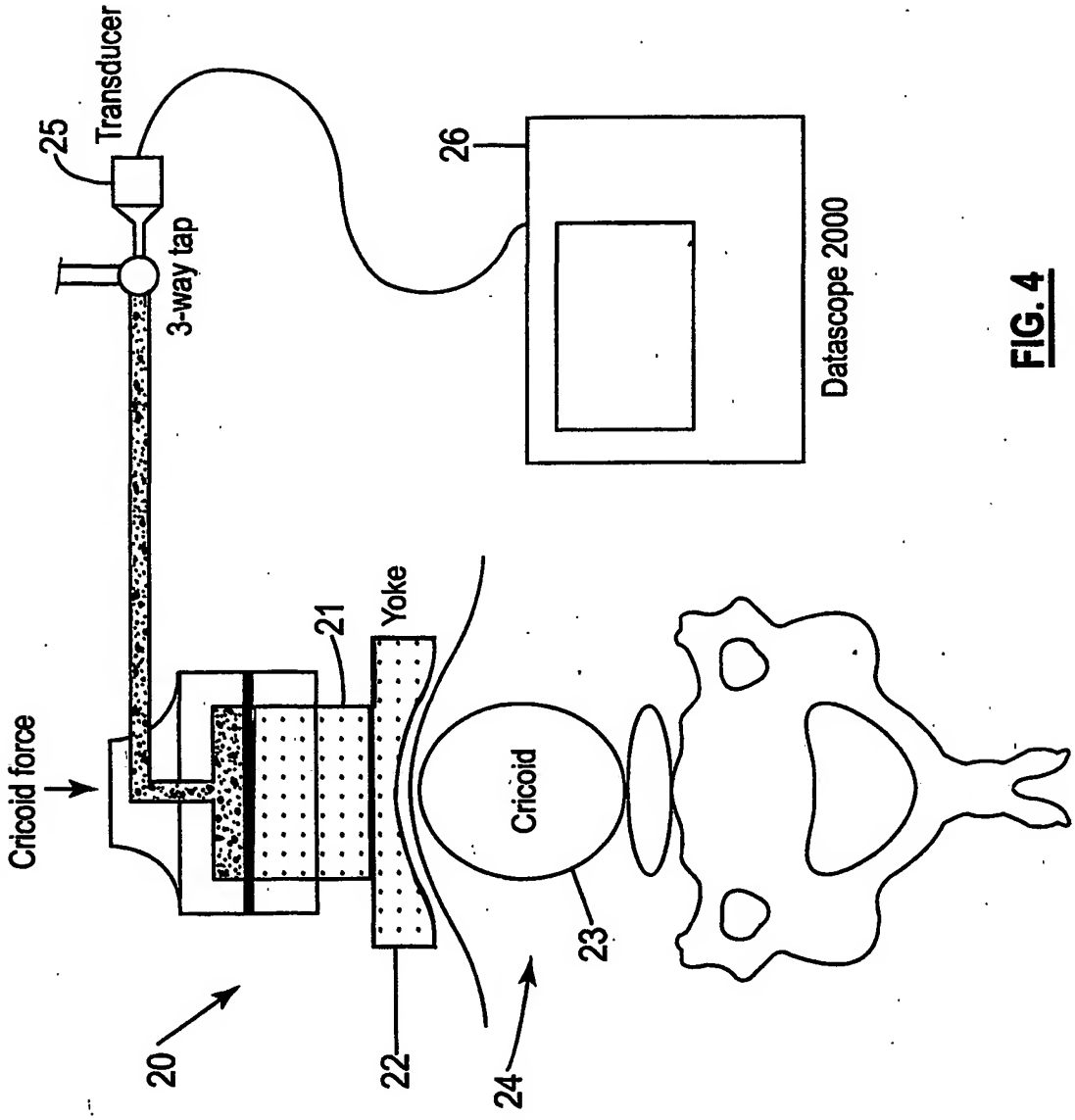
25
Transducer
3-way tap
26
Datascope 2000
Yoke
21
Cricoid force
Cricoid
23
20
22
24

FIG. 4

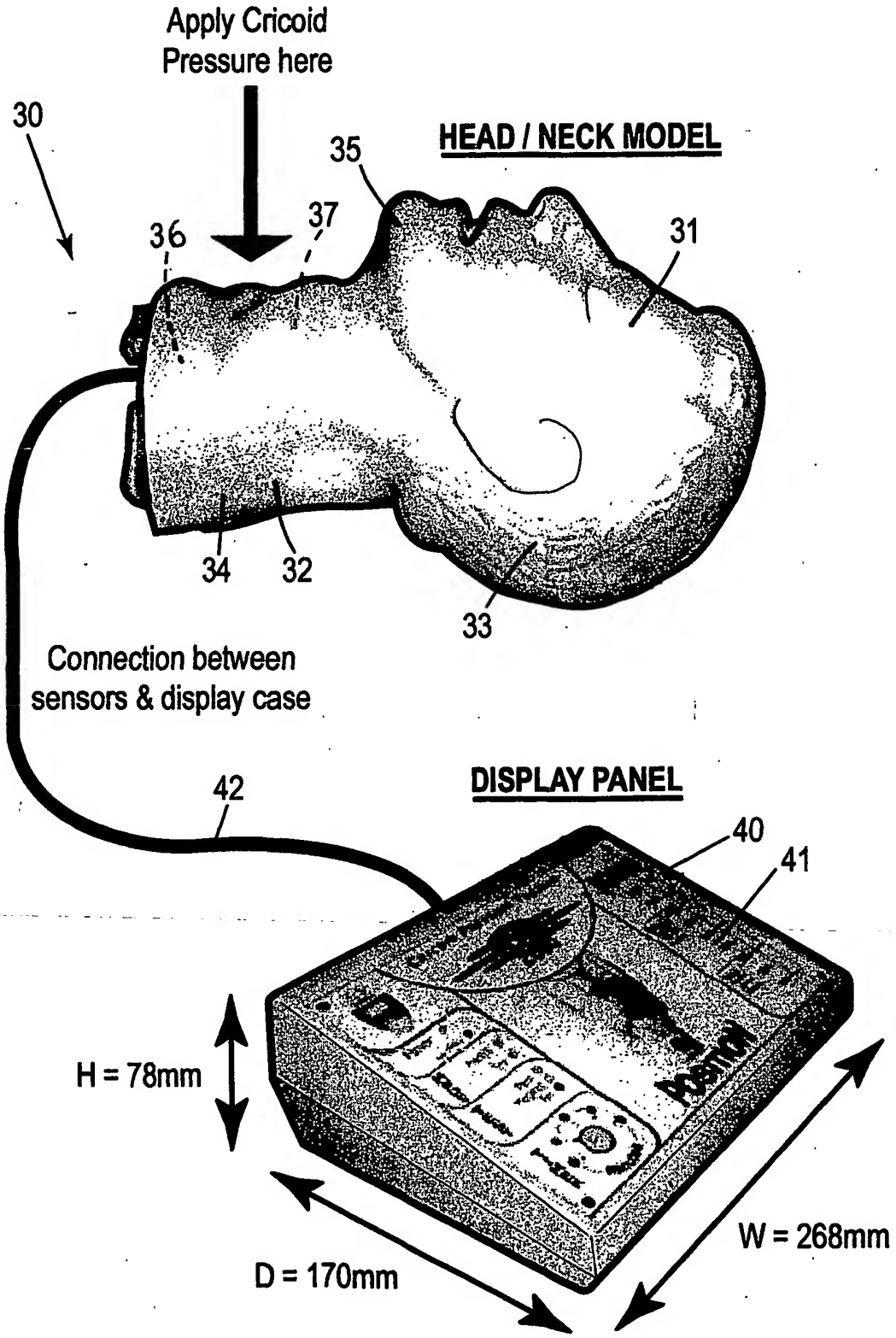
Apply Cricoid
Pressure here
30
HEAD / NECK MODEL
35
36
37
31
34
32
33
Connection between
sensors & display case
42
DISPLAY PANEL
40
41
H = 78mm
D = 170mm
W = 268mm

FIG. 5

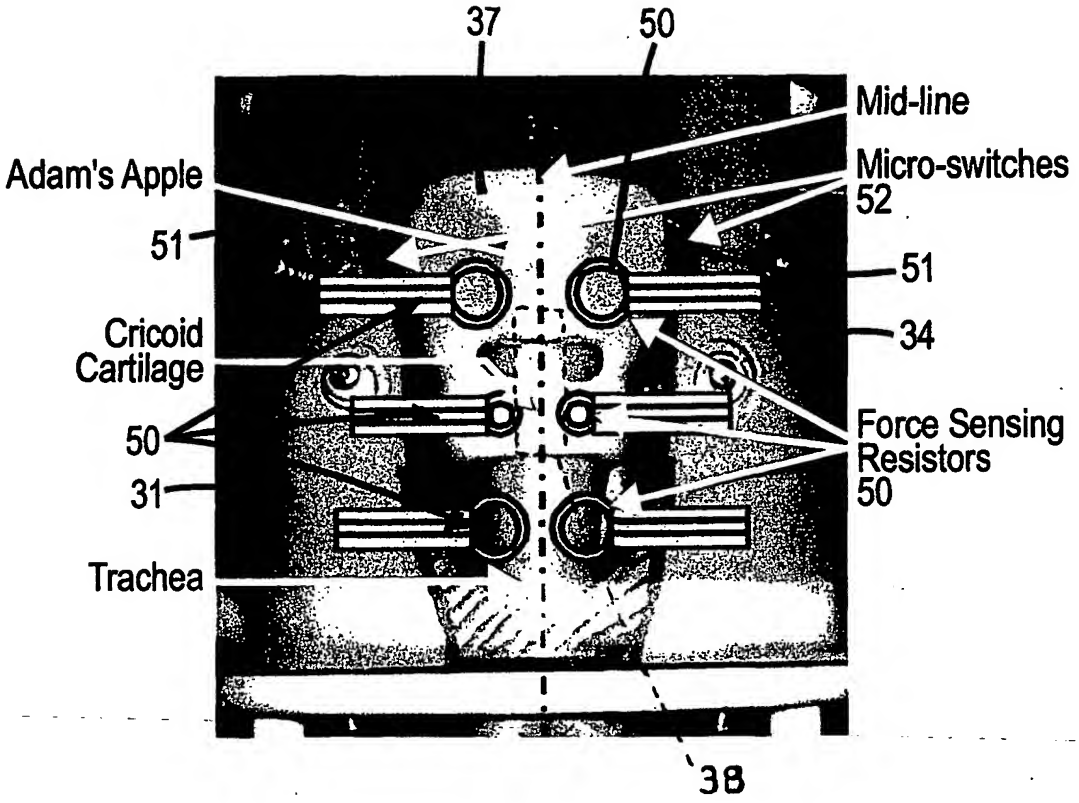
37
50
Mid-line
Adam's Apple
Micro-switches
52
51
51
Cricoid
Cartilage
34
50
Force Sensing
Resistors
50
31
Trachea
38

FIG. 6

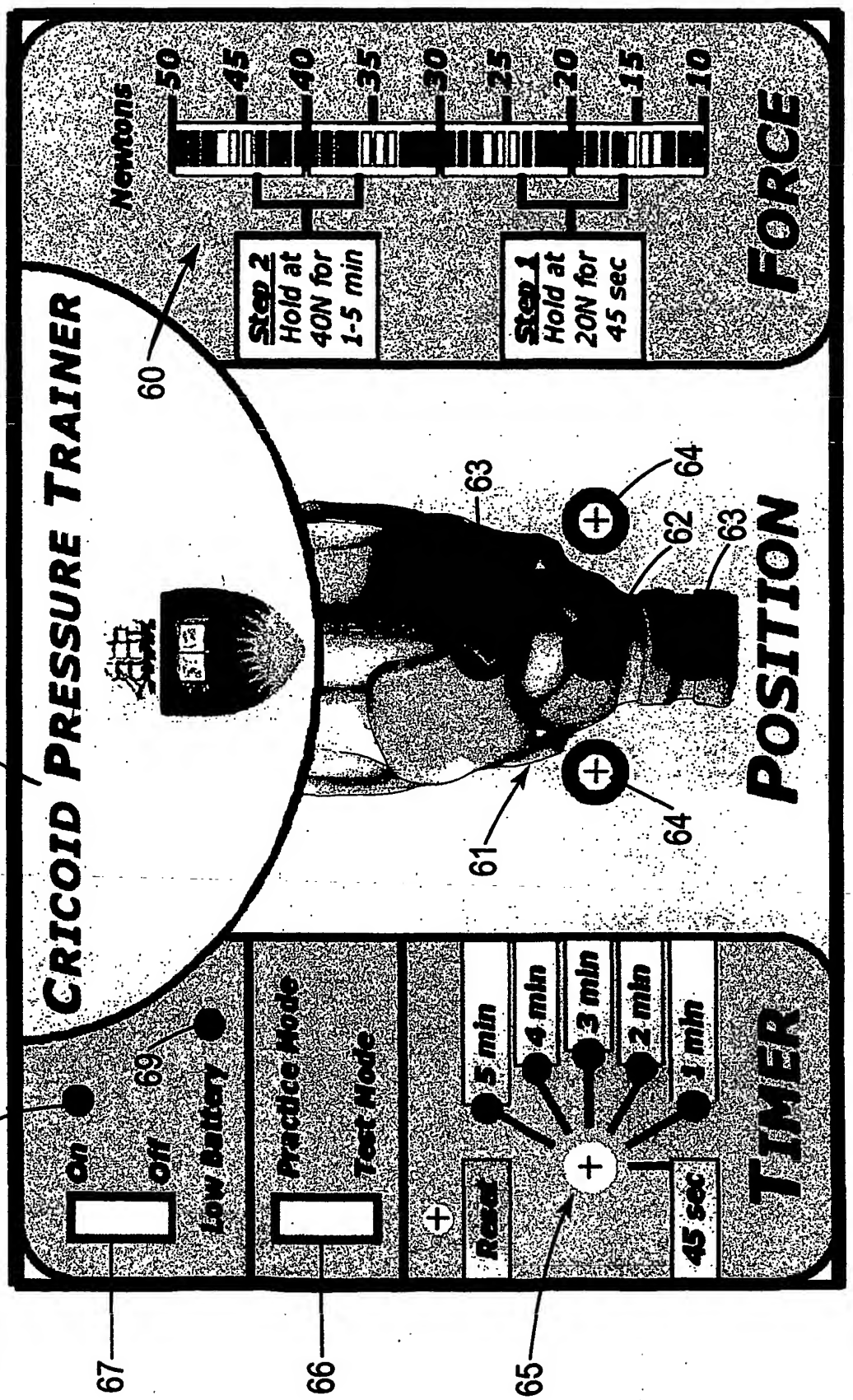
CRICOID PRESSURE TRAINER
FORCE
Newtons
50
45
40
35
30
25
20
15
10
Step 2
Hold at
40N for
1-5 min
Step 1
Hold at
20N for
45 sec
POSITION
TIMER
On
Off
Low Battery
Practice Mode
Test Mode
Read
5 min
4 min
3 min
2 min
1 min
45 sec
41
60
61
62
63
64
65
66
67
68
69

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU01/01398

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: G09B 23/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT,PUBMED (body, pressure, training)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,Y	US 6 230 574 (Rider et al.) 15 May 2001 Abstract, figures, claims	1
Y	EP 1 043 040 (Abdelatti et al.) 11 October 2000 Whole document	1,4
Y	US 5 628 230 (Flam) 13 May 1997 Abstract, figures, column 6 lines 9-28, col. 7 lines 12-33	1
A		7

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 November 2001	6 DEC 2001
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer DALE E. SIVER Telephone No : (02) 6283 2196

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU01/01398

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	AU (Application Number)61090/65 (Hesse) Granted as 289601 Published 12 January 1967 Whole document	1,4
A	Derwent Abstract for RU 2084137 (Orenburg Agric. Acad.) 20 July 1997 PAN 98-10836	1
A	US 5 483 974 (Crangle) 16 January 1996 Abstract, figures	1,5
A	DE 3834553(Kubin) 12 April 1990 Abstract, figures	1
A	US 4 331 426 (Sweeney) 25 May 1982 Abstract, figures	1

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU01/01398

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	6 230 574	NO	MEMBERS				
EP	1043040	AU	2000/22616	GB	99/07877	GB	2349500
US	5628230	AU	15359/97	WO	98/30995	EP	966734
		JP	2001/511672				
AU	61090/65	GB	23631/64		INCOMPLETE		
US	5483974	NO	MEMBERS				
DE	3834553	NO	MEMBERS				
US	4331246	NO	MEMBERS				

END OF ANNEX